UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/731,506	12/31/2012	Jon Sorenson	067191-5091-US01	2137

43850   7590   11/21/2019
Morgan, Lewis & Bockius LLP (SF)
One Market, Spear Street Tower, Suite 2800
San Francisco, CA 94105

EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
11/21/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

donald.mixon@morganlewis.com
sfipdocketing@morganlewis.com

UNITED STATES PATENT AND TRADEMARK OFFICE
_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD
_____

Ex parte JON SORENSON, SUSAN TANG, PATRICK MARKS, and
CHEN-SHAN CHIN
_____

Appeal 2018-004559
Application 13/731,506[1]
Technology Center 1600
_____

Before JOHN E. SCHNEIDER, RACHEL H. TOWNSEND, and
DAVID COTTA, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a
method for determining a consensus base call at a given location *j* in a
template sequence and an apparatus for carrying out that method. The
claims have been rejected as being directed to patent-ineligible subject
matter. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

_____

STATEMENT OF THE CASE

Automated sequencing systems are known. (Spec. ¶3.) The Specification states that

> the quality of the sequence information must be carefully monitored, and may be compromised by many factors related to the biomolecule itself or the sequencing system used, including the composition of the biomolecule (e.g., base composition of a nucleic acid molecule), experimental and systematic noise, variations in observed signal strength, and differences in reaction efficiencies.

(*Id.*) Appellant's invention is directed at a method to ultimately improve the quality of sequence data involving analysis of replicate sequence information. (*Id.* 3–4, 6, 15.)

Claims 57–61, 63, 65, 67, 68, and 71–79 are on appeal. Claim 57 is representative and reads as follows:

> 57. A method for determining a consensus base call at a given location j in a template sequence that represents a nucleic acid molecule, the method comprising:
>
> a) obtaining a plurality of reads for the template sequence using a nucleic acid sequence measurement platform;
>
> b) identifying a base in the set {A, C, G, T} for location j in the template sequence that maximizes a summation of a joint probability function summed across the plurality of reads of the nucleic acid molecule, the joint probability function comprising, for each respective read in the plurality of reads, a product of
>
> > (A) a forward path probability P that is a summation of a first set of probabilities, each probability in the first set of probabilities for a different candidate sequence for the template sequence in a plurality of candidate sequences for the template sequence given (i) the respective read, (ii) the respective candidate sequence, and (iii) an error model H associated with the

plurality of reads, wherein the forward path probability samples position j-1 of each candidate sequence in the plurality of candidate sequences, and

(B) a backward path probability Q that is a summation of a second set of probabilities, each probability in the second set of probabilities for a different respective candidate sequence in the plurality of candidate sequences given (i) the respective read, (ii) the respective candidate sequence, and (iii) the error model H, wherein the backward path probability samples position j+1 of each candidate sequence in the second plurality of candidate sequences; and

c) deeming the base identified in b) as the consensus base call at the given location j in the template sequence for the nucleic acid molecule, wherein the obtaining a) and identifying b) are performed on a suitably programmed computer.

(Appeal Br. 28.)

The following ground of rejection by the Examiner is before us on review:

Claims 57–61, 63, 65, 67, 68, and 71–79 under 35 U.S.C. § 101 as being directed to patent ineligible subject matter.

DISCUSSION

35 U.S.C. § 101 defines patent-eligible subject matter. The Supreme Court has carved out exceptions to what would otherwise appear to be within the literal scope of § 101. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). These exceptions include claims "directed to" an abstract idea. *Id.* at 217. This appeal involves the abstract idea exception to patent eligibility under section 101.

The Supreme Court has established a two-step framework for "distinguishing patents that claim laws of nature, natural phenomena, and

abstract ideas from those that claim patent-eligible applications of those concepts." *Id.* "First, we determine whether the claims at issue are directed to" a patent-ineligible concept. *Id.* If so, "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78–79 (2012)).

The PTO issued the *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance"), indicating how the PTO would now analyze patent eligibility under the Supreme Court's two-step framework. 84 Fed. Reg. 50–57 (January 7, 2019). Applying the Guidance, we agree with the Examiner that the pending claims are directed to patent ineligible subject matter.

The Examiner explains that the claims are not drawn to nucleic acid sequencing but to "'determining a consensus base call at a given location j in a template sequence that represents a nucleic acid molecule.'" (Final Action 9.) The Examiner finds that the claims involve data analysis that "is abstract, as it involves mathematical manipulation of [gathered] nucleic acid sequence *data*." (*Id.* at 9–10; *see also id.* at 3 ("the instant claims include limitations directed to the abstract ideas which are the recitation of mathematical calculations and/or relationships recited in the claims.").) The abstract ideas/judicially excepted subject matter specifically identified by the Examiner are in step (b) of claim 57: the step of "identifying a base in the set . . . ." This step involves "maximiz[ing] a summation of a joint probability summed across the plurality of reads of the nucleic acid molecule" where the joint probability function for each read comprises a "product of '(A) a

forward path probability P that is a summation of a first set of probabilities . . . '; [and] '(B) a backward path probability Q that is a summation of a second set of probabilities. . . '.'" (Final Action 3.)

The Examiner finds that the claims "do not include *additional elements* that are sufficient to amount to 'significantly more' than the recited judicial exceptions because the *additional elements* or combination of elements," include a data gathering step (obtaining a plurality of reads for the template sequence) that is routine and conventional in the art and because the "deeming the base" step is "merely 'applying' the judicial exception [and] does not provide significantly more." (*Id.* at 5.)

Appellant argues claims 57–61, 63, 65, 67, 68, and 71–79 together. We designate claim 57 as representative.

STEP 2A, Prong One:

Under the Guidance, in determining what concept a claim is "directed to" in step one of the Supreme Court's two-step framework, we first look to whether the claim recites any judicial exceptions, such as a mathematical concept (including mathematical relationships, mathematical formulas or equations, and mathematical calculations) or a mental process (including observation, evaluation, and judgment). Guidance at 52, 54 (Step 2A, Prong One). As the Examiner correctly observed, claim 57 recites mathematical calculations, including sums and products, i.e., "(b) identifying a base in the set . . . for location j in the template sequence that maximizes a summation of a joint probability function summed across the plurality of reads. . . the joint probability function comprising . . . a product of . . . (A) . . . and (B)", "(A) a forward path probability P that is a summation of a first set of

probabilities . . .” and “(B) a backward path probability Q that is a summation of a second set of probabilities . . . .”

In addition, we note that claim 57 also recites mental processes, namely “identifying a base in the set” and “deeming the base identified in b) as the consensus base call.” That is the “deeming” step is a process that, under its broadest reasonable interpretation, covers performance of the limitation in the mind. Similarly, the “identifying” step is a process that, under its broadest reasonable interpretation, covers a visual observation.

Appellant does not dispute that the claim recites mathematical calculations, conceding, in fact, that claim 57 “concerns the handling of a plurality of sequence reads for template sequence and *the computation* of a joint probability junction.” (Appeal Br. 17 (emphasis added).) Appellant argues instead that the claim as a whole is not an abstract idea because it includes data acquisition via “multiple reads for the very same template” that “sets it apart from other alignment problems” (*id.* at 14), that the best call analysis for position j is dependent on positions j+1 and j-1 in contrast to the prior art independent analysis (*id.* at 14–15), and the best call analysis “takes into consideration the error mode of a given sequencing technology used to obtain the plurality o[f] reads” (*id.* at 15–17). We will address the foregoing in the subsequent analysis.

STEP 2A, Prong Two:

Having made the determination that claim 57 recites judicial exceptions of mathematical concepts and mental processes, under the Guidance, we next examine whether there are additional elements *beyond* the recited judicial exceptions that integrate those exceptions into a practical application. Under the Guidance, this is referred to as the “Prong Two”

inquiry under "Step 2A." Guidance at 54–55. That is, under the Prong Two analysis we look to whether the claim as a whole "appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception." *Id.*

In performing this analysis, we are mindful that "a claim is not patent eligible merely because it applies an abstract idea in a narrow way." *BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1287 (Fed. Cir. 2018). Thus, for example, the Supreme Court in *Parker v. Flook*, 437 U.S. 584 (1978), found the use of a novel mathematical algorithm in a process for adjusting alarm limits, which limits signal inefficiency or danger when exceeded, in catalytic conversion of hydrocarbons patent ineligible. *Mayo*, 566 U.S. at 80 (discussing *Flook*, 437 U.S. at 585–87). The process included "the steps of: (1) measuring the current level of the variable, e.g., the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm-limit values." *Id.*[2] In light of this, we do not find persuasive Appellant's argument that because claim 57 is "directed to the specific technological process of nucleic acid sequencing," it is directed to patent eligible subject matter (Appeal Br. 20).

_____

[2] We note that claim 65 recites an apparatus that includes memory with one or more programs stored therein and one or more processors that execute the program(s) where the program(s) include instructions to carry out the method steps as set forth in claim 57. We note that the Supreme Court has stated that "simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle." *Id.* at 84 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).)

In contrast to *Flook*, the Supreme Court in *Diamond v. Diehr*, 450
U.S. 175 (1981), found the overall physical and chemical process for
molding precision synthetic rubber "patent eligible because of the way the
additional steps of the process integrated the equation into the process as a
whole." *See e.g.*, *Mayo*, 566 U.S. at 80 (discussing *Diehr*, 450 U.S. at 177–
79); *Recognicorp, LLC v. Nintendo Co. Ltd.*, 855 F.3d 1322, 1326 (Fed. Cir.
2017) ("In confirming patentability, the Supreme Court focused not on the
presence of a mathematical formula but on the subject matter of the claims
as a whole. [*Diehr*, 450 U.S.] at 192."). The process included "installing
rubber in a press, closing the mold, constantly determining the temperature
of the mold, constantly recalculating the appropriate cure time through the
use of the formula and a digital computer, and automatically opening the
press at the proper time." *Mayo*, 566 U.S. at 80–81. The Court stated: "[A]
claim containing a mathematical formula" satisfies § 101 when it
"implements or applies that formula in a structure or process which, when
considered as a whole, is performing a function which the patent laws were
designed to protect, (*e.g.,* transforming or reducing an article to a different
state or thing)." *Diehr*, 450 U.S. at 192. Outside of the math, *Diehr* was
directed to a process that was directed to otherwise eligible subject matter,
an industrial process for the molding of rubber products. *Id.* at 192–93; *see*
Thales Visionix Inc. v. United States, 850 F.3d 1343, 1348 (Fed. Cir. 2017)
("In terms of the modern day *Alice* test, the *Diehr* claims were directed to an
improvement in the rubber curing process, not a mathematical formula.").

Unlike the process performed in *Diehr*, the process in Appellant's
claim 57 does not involve additional elements beyond the recited

mathematical concepts and mental processes to transform or reduce an article into a different state or thing.

Contrary to Appellant's argument, we do not find claim 57 provides specific mechanisms that are significantly more than the abstract ideas (Appeal Br. 25; Reply Br. 3–4). We find that there is only one limitation that is not one of the identified abstract ideas, namely step "a) obtaining a plurality of reads for the template sequence using a measurement platform." However, this is a pre-solution data gathering step (*see* MPEP § 2106.05(g) ("[a]n example of pre-solution activity is a step of gathering data for use in a claimed process.")), that does not apply any of the abstract ideas in a meaningful way, but instead simply "generally link[s] the use of a judicial exception to a particular technological environment or field of use." Guidance, 84 Fed. Reg. at 55 (citing MPEP § 2016.05(h)); *see also In re Grams*, 888 F.2d 835, 840 (Fed. Cir. 1989) ("The presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory."). Moreover, we note that Appellant's Specification indicates that "[e]ssentially any technology capable of generating sequence data from biomolecules may be used to generate the replicate sequence reads." (Spec. ¶ 39.)

Appellant's arguments that the best call analysis is dependent on positions $j+1$ and j-1 (Appeal Br. 14–15), and that the best call analysis "takes into consideration the error mode of a given sequencing technology" (*id.* at 15–17), unlike the prior art, does not establish that there are additional elements beyond the recited judicial exceptions that integrate those exceptions into a practical application. Appellant's arguments simply indicate that the mathematics (which is the specific mechanism for

determining the consensus base call) involved in the claimed method are an improved algorithm that improves the accuracy of the consensus base call at a given location *j* in a template base sequence. (*See* Appeal Br. 13–17, 25; see also Reply Br. 3–5.) In this respect, this case is like *Flook*. In *Flook*, the "only difference between the conventional methods of changing alarm limits and that described in respondent's application rest[ed] in the second step— the mathematical algorithm or formula." 437 U.S. at 585–86. In *Flook*, the court found that the claimed subject matter "simply provides a new and presumably better method for calculating alarm limit values" and, thus, was not directed to patent eligible subject matter. *Id.* at 595 (explaining "'if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.'"). The court found that the use of that method to adjust an alarm limit did not render the method patent eligible. *Id.* We conclude that, like *Flook*, the claimed method is to a "new and presumably better" algorithm, and the only difference between the claimed method and conventional methods lies in the algorithms used. As in *Flook*, the judicially excepted subject matter generates information: here the probability of correctness of the base for location *j*, in *Flook*, an alarm value. In *Flook*, the information generated was used to "adjust" an alarm value. Here, the information generated is used to select the identity of the base for location *j*. In neither case does the use of the information generated by the excepted subject matter integrate the judicially excepted subject matter into a practical application.

Appellant's reliance on *McRO, Inc. v. Bandai Namco Games America, Inc.*, 837 F.3d 1299 (Fed. Cir. 2016) (Appeal Br. 18–22, Reply Br.

6–7) to argue its claim is not directed to an abstract idea is unavailing. In *McRO*, prior to the claimed invention, character facial expressions and lip synchronization were accomplished by human animators, with the assistance of a computer, where animators set appropriate parameters at certain time points, a so-called "keyframe" approach. *McRO*, 837 F.3d. at 1305. The animators, using a computer, manually determined the appropriate parameters to set for each keyframe based on the phoneme timings in a time-aligned phonetic transcript. *Id.* The invention in *McRO* that resulted in an improvement to the field of computer animation was removal of the human element to the keyframe process by using rules, rather than human animators, which automatically set the parameters. *Id.* at 1313. The rules in *McRO*, thus, allowed the *computer* to produce accurate and realistic synchronization in animated characters that could only previously be produced by humans. The claims here do not relate to any such rules replacing human action to allow computers to perform automatically what previously required human interaction. That is, neither the claim, nor the Specification provide for rules that allow for a computer to act in a way that it could not before without human interaction.

Appellant further argues that "claim 57 would not preempt the computer implementation of any known commercial, industrial or scientific practice or methodology, as it incorporates a novel and non-obvious solution to a technical problem (Appeal Br. 17, *see also id.* at 22–24) and thus, the claim should be deemed directed to patent eligible subject matter. We do not find this argument persuasive. Preemption is sufficient to render a claim ineligible under § 101, but its absence does not require a conclusion of patent eligibility. *Athena Diagnostics, Inc. v. Mayo Collab. Servs., LLC,*

915 F.3d 743, 752 (Fed. Cir. 2019) (citing *Flook*, 409 U.S. at 71–72 (holding claim involving mathematical formula invalid under § 101 that did not preempt a mathematical formula); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 764 n.4 (Fed. Cir. 2014).

STEP 2B

We next turn to Step 2B to evaluate whether the claims provide an inventive concept. Guidance at 54.

Under the Guidance, we must consider in Step 2B whether an additional element or combination of elements: (1) "adds a specific limitation or combination of limitations that are not well-understood, routine, conventional activity in the field, which is indicative that an inventive concept may be present;" or (2) "simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, which is indicative that an inventive concept may not be present." *Id.*

The analysis is not an evaluation of novelty or non-obviousness, but, rather, a search for "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Alice*, 573 U.S. at 217–218 (alteration in original). A novel and nonobvious claim directed to a purely abstract idea is, nonetheless, patent-ineligible. *See Mayo*, 566 U.S. at 90. Thus, that there is no evidence provided by the Examiner "that the process required by the claims is the same as any process previously used in sequence determination and conducted by similar or other means" (Reply

Br. 5), is insufficient to establish the claim is directed to something
significantly more than the patent ineligible concept itself.

As discussed above, the collection of multiple reads is described in
Appellant's Specification to be by any routine methodology. Appellant's
mathematical algorithm to process the data in order to identify the base for
location *j* may be novel, but that by itself is insufficient to render the claim
directed to that judicial exception patent eligible for the reasons discussed
above. *See Flook*, 437 U.S. at 591–92 (

> The process itself, not merely the mathematical algorithm, must
> be new and useful. Indeed, the novelty of the mathematical
> algorithm is not a determining factor at all. Whether the
> algorithm was in fact known or unknown at the time of the
> claimed invention, as one of the "basic tools of scientific and
> technological work," see *Gottschalk v. Benson*, 409 U.S., at 67,
> 93 S.Ct., at 255, it is treated as though it were a familiar part of
> the prior art.);

see also id. at 594–95 ("Respondent's application simply provides a new and
presumably better method for calculating alarm limit values.").

Furthermore, while it may be the case that the methodology improves
the accuracy of the determination of the base call at a given location *j* in a
template sequence (Reply Br. 6), there is no technological improvement.
There is no contention or evidence that the functioning of a computer or
other device is improved, nor is there a contention or evidence that the claim
solves a problem with a system that analyzes sequence data. *Cf. Amdocs
Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1300–02 (Fed. Cir. 2016)
(determining the claimed invention creating a distributed architecture
"entailed an unconventional technological solution (enhancing data in a
distributed fashion) to a technological problem (massive record flows [that]
previously required massive databases)" that "improve[d] the performance

of the system itself"); *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1348–49 (Fed. Cir. 2017) (determining that a system for tracking motion of an object via a first inertial sensor on a moving object, a second inertial sensor on a moving reference frame, and an element adapted to receive signals from the inertial sensors and determine an orientation of the object relative to the moving reference frame, was not directed to an abstract idea because the system used its inertial sensors in a non-conventional manner to determine the relative position and orientation of a moving object on a moving reference frame). Here, the improvement relates to improved data analysis from using a new algorithm, not new technology. As Appellant acknowledges, Appellant's claims are directed to "a method of calculating a result within the context of a specific set of limiting rules," (Reply Br. 8) i.e., mathematical algorithms. (*See* Appeal Br. 25:

> As discussed above, and as set forth in the specification as noted above, consideration of positions *j-1* and *j+1* of the template sequence when calling position *j* of template sequence allows for the use of more robust error models and hence more accurate calling of the template sequence. . . .

(and noting the specific calculations required by the claim as being the "specific mechanisms" by which the more accurate calling is achieved).)

Because Appellant's independent claim 57 is directed to a patent-ineligible abstract concept, does not include additional elements that integrate the judicial exception into a practical application, and does not add a specific limitation beyond the judicial exception that is not "well-understood, routine, [and] conventional," we sustain the Examiner's

rejection of the claims under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 58–61, 63, 67, 68, and 71–79 have not been argued separately and therefore fall with claims 57 and 65. 37 C.F.R. § 41.37(c)(1)(iv).

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
57–61, 63, 65, 67, 68, 71–79	101	Eligibility/Patent Ineligible subject matter	57–61, 63, 65, 67, 68, 71–79	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED